EXHIBIT 32

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A. Plaintiff, vs. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. 3:11-CV-02506-JAP-DEA

DEPOSITION OF DR. STEPHEN R. BYRN

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before TAB PREWETT, a Registered Professional Reporter, a Certified LiveNote Reporter, and Notary Public, held at the Offices of HOGAN LOVELLS US LLP, 875 Third Avenue, New York, New York 10022, on Friday, June 8, 2012, commencing at 10 a.m.

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personal information, what a person skilled in the art knows.
Q. But you have presented no documentary proof to support your claim?
MS. CHOW: Objection to the form.
A. I mean, I don't know. There weren't any -- people just knew this. There weren't any publications. It was just known.
Q. And so then the -- also, the USP that you have attached to your declaration -- well, we'll get to that in a second -- it's not specific to any particular device, right?
A. Correct. That's because of the -- one thing that we are missing here is the definitions of what "precision" and "error" is. There are really four levels of precision that one deals with when they do particle size. And you need to know and understand those in order to interpret the claims and the data.
Q. Okay. Now, the claim is not limited in terms of how you measure particle size. You can measure it using any other

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technique, including laser diffraction, right?
A. Correct.
Q. Okay. But your construction is dependent upon the standard deviation of laser diffraction. So how do you reconcile the two, a claim that is not limited to the way you measure it versus construing the term limited to a way it's measured?
MS. CHOW: Objection to the form.
A. I wanted to do -- be conservative and give a number that was a low number, a conservative number, because of claim construction and because it's a legal issue. So I took a low number. Probably, in reality, it's slightly higher than 10 percent, but that's how I -- that was my approach.
Q. So you're correlating -- with all of the other methods of measuring particle size, you are correlating the laser diffraction to all of those other methods?
MS. CHOW: Objection to the form.
A. No, I am saying that, based on my

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experience of skill in the art, that, when a person skilled in the art reads the number, 400 microns they think conservatively plus or minus 10 percent and, you know, there are --
Q. I'm sorry --
A. -- they think conservatively really. I can just stop there.
Q. All right. Let me just give you what is marked as D 27.
(Exhibit No. D 27, Excerpt from Physical Pharmacy, is marked by the reporter for identification.)
Q. Dr. Byrn, where I am confused is that you are applying a USP -- the portion of the USP describing the standard deviation for laser diffraction. And am I correct you are applying that across the board to every other type of measurement that is being used to determine particle size that is out there? Am I correct about that?
MS. CHOW: Objection to the form.
A. No. What I am saying -- I am not

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applying that. I am saying a person skilled in the art reading "400" would read "plus or minus 10 percent" conservatively.
Q. Regardless of what device you used to measure it?
MS. CHOW: Objection to the form.
Q. Is that your testimony?
A. Well, when you read a patent the way I approached it or my analysis, I said a person skilled in the art is going to read this, and they are going to want to figure out how to make the measurement to be -- whether they're within or without the patent.
And so they would read this, and they would say it can be measured by laser diffraction; but it could also be measured by other means. And then we have the number, 400 microns.
So that means to me, in my opinion, a person skilled in the art reading this would say that it's 400 plus or minus 10 percent. And I think that's a conservative number.

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Q. And that's regardless of the means in which you measure the particle size?
MS. CHOW: Objection to the form.
A. Well, I didn't ignore the means. I just said, regardless, they would look at all of these options, and they would realize that it's plus or minus 10 percent as a reasonable number and a proper claim construction for that number. And the court -- the court already agreed with me.
Q. I understand that. We are going to have -- we'll have a different hearing, and perhaps we have a different approach.
A. Okay.
Q. But you realize that the only documentation you presented to substantiate the plus or minus 10 percent was a document that was dated after the filing date, and was specific only to laser diffraction, correct?
MS. CHOW: Objection to the form. Asked and answered.
Q. And there is nothing in that

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document suggesting -- indicating otherwise that that plus or minus 10 percent would apply to any other means of measuring particle size distribution; isn't that correct?
MS. CHOW: Objection to the form. Asked and answered.
MR. PARKER: It's not asked and answered.
A. Although all that's correct, as I explained, I -- my analysis of the claim was based on my experience. And then the plus or minus 10 percent is a conservative number that I put on it that agrees with the USP. But I think it's a conservative number for the time that that was.
Another point is there are four types of error we are dealing with it. So the Helos Rodos error is the smallest, by far. The other three are much bigger. And those -- you know, I use those in my analysis.
Q. What other types of errors are you talking about?

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A. So if you look in the Snorek paper, it's pretty well-explained there. And it's also explained -- I think it's best explained in the Snorek paper. There is --
MS. CHOW: Has that been marked?
A. If you can hand me the Snorek paper, I can go through it.
Q. I will do that.
A. That would be a good way for me to explain it because I think we are getting mixed up on what the error numbers are out there and what the meaning of them are.
Q. By the way, I am handing the witness what has been marked as D 28, which is the -- I think we all believe is the Snorek reference.
(Exhibit No. D 28, Snorek Reference, is marked by the reporter for identification.)
Q. Also, for the sake of completeness, I will hand you what has been marked as D 29, which is the portion of the USP that I believe

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is part of your declaration.
Let me find a place to put this.
(Exhibit No. D 29, Portion of USP that is part of Dr. Byrn's Declaration, is marked by the reporter for identification.)
Q. But just for some foundation, I think this will help.
On Exhibit D 27, Dr. Byrn, you will -- it's an excerpt from Physical Pharmacy; and the pages reveal different means of measuring particle size distribution. Do you see that -- which includes -- correct me if I'm wrong -- optical microscopy, sieving, sedimentation -- and, yes, it includes at least those three means that I'm aware of. If I am wrong, you can correct me.
A. No, correct.
And these methods, these three are wider errors than laser diffraction.
Q. Even sieving?
A. Yes. Sure. Because consider you have a needle particle, and you have some round

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particles. The round particles will fall through. The needle won't. And you will get a -- a distortion in the particle size.

So sieving is not considered an accurate method, and it wouldn't work for small particles, either like cement, like the -- like this project, you couldn't even sieve. You couldn't come close.

Q. You realize in the '994 specification that sieving is the method that they -- that they ended up using?

MS. CHOW: Objection to the form.

A. Well, they just say, for example, Helos Rodos. I think they use some sieving, also. But I think the errors of sieving are larger than 10 percent, in my experience.

Q. So, again, I am just trying to be clear now. Your position is 400 microns or less plus or minus 10 percent, as we just talked about, is based on the information, at least in part, what's in the USP as it concerned laser diffraction?

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MS. CHOW: Objection to the form.

A. No. In my plus or minus 10 percent, my analysis is based on my own experience.

Q. So your plus or minus 10 percent -- I didn't know this; this is the first time I am hearing this is all encompassing -- it encompasses all the methods of measuring?

A. And it's a conservative number.

Q. That's your position?

A. That's my position.

Q. Okay.

A. And I would further add that, generally, laser diffraction is the best method, the most precise method. So the numbers that Snorek's talking about, and USP, laser diffraction are the numbers that are most precise. So other methods -- and that's one of the reasons the USP has focused in recent years on the laser diffraction.

Q. Are you aware of any published information that would contradict the

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information that is provided in the Helos Rodos materials with respect to standard deviation?

I understand your opinions and experience. But are you aware of any published information which actually went out and took on the task of actually seeing how precise this information is or can be?

MS. CHOW: Objection to the form.

A. Yes. That's the -- well, the --

Q. Where can I find that information?

A. Okay, it's NIST -- it's a document called capital N-I-S-T-I-R, all capital letters, 6883, is one document. And the reason I found that document is that it's on cement. I don't think cement is a proper comparison to drugs.

So on the face of this, I don't think it's the right way to do it. But if you look at that document, what they did is they took four or five samples of cement, the National Institute of Standards. They sent them to 25 labs, who ran laser diffraction particle size, not just on a Helos Rodos, but bigger,

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wider still, and measured the average and the standard deviation. And when you look at the data, some of it is as high -- the deviation is as high as 65 percent, not 10 percent, but 65 percent.

So that's only with cement, and it's only on laser diffraction.

You have other data in those things on other measurements. So that alone tells me that this isn't right, and it's not -- it was known that this is not right. This isn't the precision of the method. This is -- and I am going to get to that -- I am going to get to the errors. If you want me to get to the errors, I will explain why it isn't the right way to do it.

You want me to keep going, or you want to ask me a question?

Q. No, I want to stop there. I am going to get to that.

This document -- is this document attached to your declaration?

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A. No, I found it after I reviewed Dr. Mumper's declaration and was -- saw that he was talking about cement. And I said, "Well, what is out there about cement," because, as I said, I wouldn't have used cement when I wrote my declaration.

Q. Now, was this dated prior to 1999?

A. I don't remember the date. I think it's more like 2000. It could be '99. It could be -- I don't remember the date. But there's NIST -- there are other NIST measurements going on in that time frame.

Q. But isn't the use of cement -- I mean, that's more or less -- it's like a control standard; isn't it?

A. Well, it's a lot more precise than drugs. The numbers you get from cement -- especially if you sit at the instrument company and measure it a few hundred times, the numbers you get are a lot more precise than you would for a drug.

I'm going to explain that if you --

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maybe I should just go ahead so you see what I am talking about.

Q. Well, why don't you try -- if you want, try to explain it.

A. All right. I can try to do it briefly. If you turn to page 1460 of Snorek -- pardon me, 1462, in the bottom right-hand corner, starting there and going over to 1463 in the first column, she lists three -- under "Validation," she lists three ways to figure out error. And in the first one is where the 10 percent comes from.

The first one, precision repeatability. So that's the repeatability of a measurement. The precision of a set of measurements should be obtained using one analyst conducting the method as written. And then she goes over the method. The measurement should be made in a single lab on a single apparatus. And then the next bullet, from one lot obtain replicant measurements.

So you take one lot. You take

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replicant measurements. And you determine the average and the standard deviation. It's 10 percent. That's where the 10 percent number is.

This measurement that these guys are doing is the instrument error on one sample of one lot submitted many, many times. It's smaller than this number one method.

Q. Much smaller.

A. Much smaller. Because it should be, because you are just putting the same thing in every time. If the instrument doesn't get the right answer and you just repeatedly put the same thing in, you have got serious problems.

So -- but this is not the error, in my opinion, that the patent is talking about.

If we go to "Intermediate precision," the next bullet, the measurement should be made in the same lab on different days and on more than one instrument.

So now we are doing more than one instrument. And then if you go down to

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reproducibility, it is a precision of the test results made by analysis of same samples under a variety of conditions. So there's levels of error.

What this is is the most precise, really low. I actually took the next most precise and used it. But there are two higher than that. I don't think it'S indefinite. I don't think the patent is indefinite. But I think that the 10 percent is conservative based on this. And I don't think this is a reliable thing.

Q. And you -- well, you said basically the error in the patent is talking about.

A. Well, I don't mean the error in the patent. I mean the error of the plus or minus 10 percent that a person skilled in the art. I think that's conservative.

Q. So based on what you have described of what was going on prior to when this USP criteria came out, you are saying the standard of error was pretty large, or it was, as you put

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Snorek is talking about.
Q. Forget about Snorek for a second, please. I will go to that in minute.
On the USP, we are not talking about -- when it talks about "replicates," we are not talking about instrument precision. We are simply talking about, you get a sample; you want to report that measurement; and in order to show that it's at least accurate under this criteria, you would have to measure that same sample three times. And then you look to see -- you take your central value. And then from there, you determine whether you have variation of 10 percent.
MS. CHOW: Objection to the form.
A. Not the -- not the same sample.
Q. Where is it -- okay.
A. At least three different representing samples from the same batch.
Q. The same batch. I'm sorry. I misspoke.
You take the same batch, but you

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are measuring three samples of the same batch?
A. You take three different samples out and run them -- and prepare them and run them.
Q. I understand that.
A. That's a lot different from what Helos Rodos did.
Q. Let me back up, though.
It's a lot -- what you are saying here, I just want to be clear. We are not talking about instrument precision where it says "replicates." We are talking about the precision of the actual measurement being done.
Do you agree with that?
MS. CHOW: Objection to the form.
A. I agree with that. And I think that's what the patent is talking about. The patent -- it makes little difference to a person skilled in the art what the instrument precision is. They are trying to figure out whether or not a number is within or outside the patent, so they are not worried about the instrument

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precision. They are worried about the repeatability, or even maybe more the higher level error problems like the intermediate precision, which is the next level up.
So there, the instrument precision has little to do with what the patent is talking about.
Q. So when they come up with 400 microns or less -- well, if you look at the values that they have in the '994 patent, in examples 4 through 9, am I -- is one of ordinary skill in the art to assume that is a plus or minus 10 percent value?
A. Sure. Absolutely.
Q. So -- but you have no idea back then because there was no criteria whether or not it was either the middle value, whether it was -- it was basically from the same batch measured three times; there is no indication that that was done in the patent.
MS. CHOW: Objection to the form.
A. Well, I am just saying that,

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according to my analysis and the way you would report the data and if I got a paper to review, all that put together, that, when you put a number in there, my whole analysis was plus or minus 10 percent. And that is a conservative number.
Q. But you are speculating. You are assuming that, based upon a document that is filed well after the filing that -- published after the filing date, which requires that you take three samples from a single batch and do your analysis to see what the variation is, that that was somehow applied in the context of this patent. And you have no proof of that.
MS. CHOW: Objection to the form.
A. That's why I use a conservative number. That's why I was 10 percent. I didn't want to speculate closer to what I think the real numbers are. I just used 10 percent because I thought that was a conservative number.
Q. So one of ordinary skill in the art

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(A break is taken.)
CONTINUED DIRECT EXAMINATION
BY MR. PARKER:
Q. Dr. Byrn, a while ago we talked about cushioning. You have already described it, but let me ask a question:
How would you test for cushioning?
MS. CHOW: Objection to the form.
A. I think the way Dr. Shimizu did was fine. You make tablets and then do those experiments he did.
Q. You look at the hardness?
A. No, acid resistance, and also release. Just -- yeah, I am trying to find exactly --
Q. Take your time.
A. -- what exhibit it is.
MS. CHOW: Are you looking for Dr. Shimizu?
THE WITNESS: Yes, what exhibit is that?
MR. PARKER: It should be 17.

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THE WITNESS: Here it is, remaining ratio.
Q. Okay. How was that -- that was calculated how? How was that calculated?
A. The content of the drug -- there are three things he measured: hardness, acid resistance, and remaining ratio. And there it's described that the "remaining ratio" is "a content of the drug in the collected fine granules after the dissolution test for one hour."
Q. Okay. So there are three factors: the hardness, acid resistance, and remaining ratio. Then he has a conclusion, "not more than 10 percent." Can you just explain what you understood that to mean?
A. Sorry, I didn't catch that one, that question.
Q. Okay. My question you mean?
A. Yes.
Q. So in this -- since you have the declaration in front of you, he mentioned in

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conclusions "not more than 10 percent." Do you see that? He has it in quotes.
He says:
"Acid resistance defined in USP 24" -- and it goes on -- "not more than 10 percent."
Can you just explain what that -- what that means to you?
A. I would have to check that. I mean, what I was looking at is the -- it's about half -- example B is about half as sensitive to acid as example A. I'm not sure what the "not more than 10 percent" is. I would have to look at that USP test.
Q. As far as going back to cushioning, as you stated in your declaration, I mean, a reason to expect when you -- strike that.
I just want to turn to now the -- go to Claim 1 of the '994 patent, that portion of the claim that refers to orally disintegrable tablets. Then there is a phrase, "wherein said tablet is orally disintegrable."

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Do you recall -- did you take a position on those claim terms in your declaration?
A. I don't recall that I did.
Q. Do you recall that Dr. Mumper took the position that those phrases, where he referred to "a tablet that is capable of disintegrating either in the mouth with saliva or water and then swallowed."
A. Yes.
Q. Okay. And do you agree or disagree with that interpretation?
A. I disagreed.
Q. Okay. And what is the basis of your disagreement?
A. Well, one, that it's clearly -- I think it's clearly in the mouth. One is in the abstract. It says "oral cavity" in the '994 abstract.
Q. So you are looking to the abstract as part of your basis for construing that claim term?

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A. As part of the basis.
Q. Anything else?
A. Yes, there are places, if I can -- on column 12, line 39, it says that:
"Orally disintegrable tablet of the present invention exhibits fast disintegrability or dissolubility in the oral cavity and also an appropriate strength of preparation."
Q. Okay. That's column 12, you said, line 37?
A. Line 38 or 39. It's 39, sorry. 39, 40, and 41.
Q. Okay. Anything else at this time?
A. The '632 -- are we just confined to the '994?
Q. Yes.
A. Okay.
Q. So if I can just direct your attention to column 17, line --
A. There are probably others that I didn't find.
Q. Okay. But if I can just direct

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your attention -- and if there's something else, you can just call that out. But if I can just direct your attention to column 17, line 56 -- or 57, I'm sorry, all the way down to the end.
And, quote:
"A solid pharmaceutical preparation comprising the fine granules of the invention as used for an oral disintegrable tablet can be administered without water or together with water."
Do you see that?
A. I see that.
Q. Okay. Now, the "fine granules of the invention," that is -- would you agree it's a reference to the four micrometers or less, microns or less?
MS. CHOW: Objection to the form.
A. The 400 --
Q. Right.
A. -- plus or minus 10 percent microns or less.
Q. And then it also states that it

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could be administered without water. And that would --
A. Well, that would be -- to me, that's just putting it in the mouth.
Q. That's right. If it's together with water, that would include with water, correct?
A. Well, that's what it says. But it defined "orally disintegrable tablet" as in the oral cavity. So I mean, there, I just look at this -- this isn't defining the tablet. It's just saying that you can also administer without water.
Q. Okay.
A. But the defined characteristic is dissolubility and disintegrability in the oral cavity.
Q. Are you now back on column 12?
A. Yes.
Q. Again, I know it's tough to -- just the line number, where is that again?
A. 39, 40, and 41.

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So this doesn't change my opinion of what that definition means.
Q. It says that it "exhibits fast disintegrability or dissolubility in the oral cavity," and it goes on.
A. But I mean, it's talking about the mouth.
Q. Right.
A. No matter what, it's talking about the mouth.
Q. Right. Would you agree, though, in column 17 and even down below that, it's talking inside and outside of the mouth?
MS. CHOW: Objection to the form.
Q. 17, lines 56 down to 67.
A. To line, which 67? 6-7?
Q. Yes.
A. Well, I mean, it's almost what I would call an off-label use. It's not the main use. It's not the defining use. I don't look at this as -- I am not even sure, you know, how to react further other than to me the defining